FIGURE 1

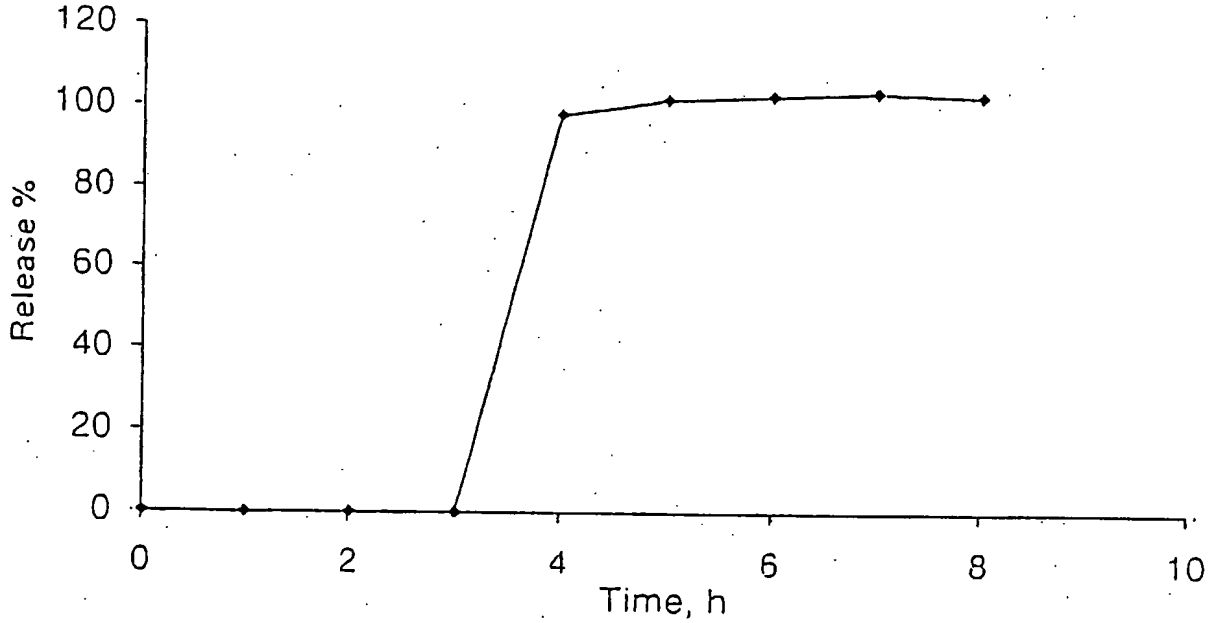


FIGURE 2

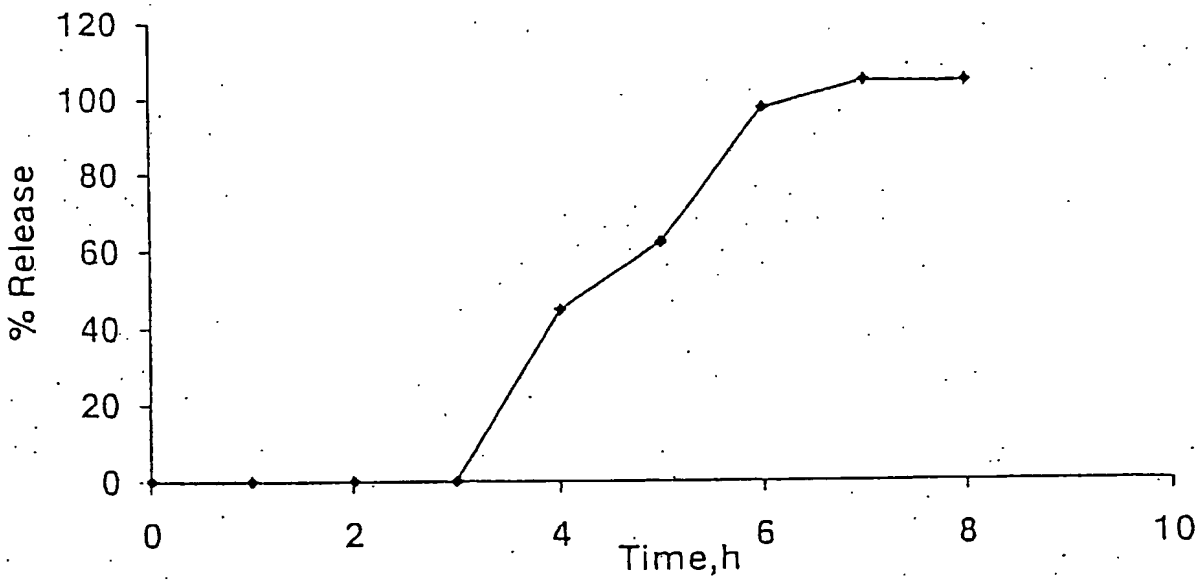


FIGURE 3

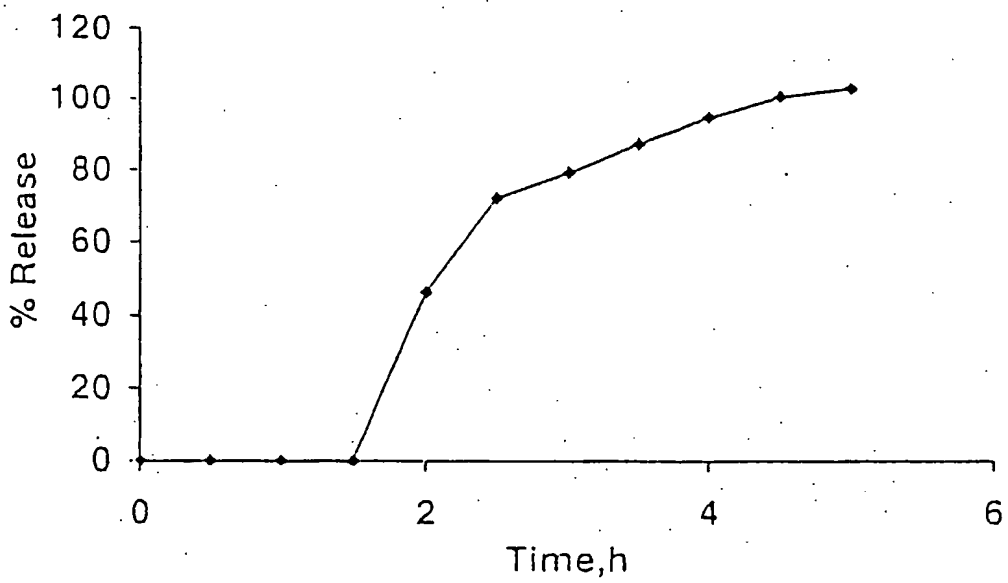


FIGURE 4

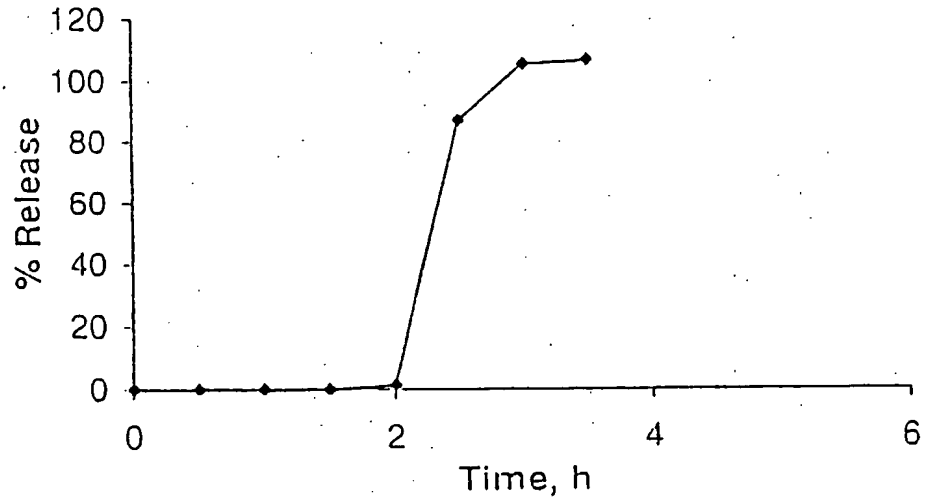


FIGURE 5

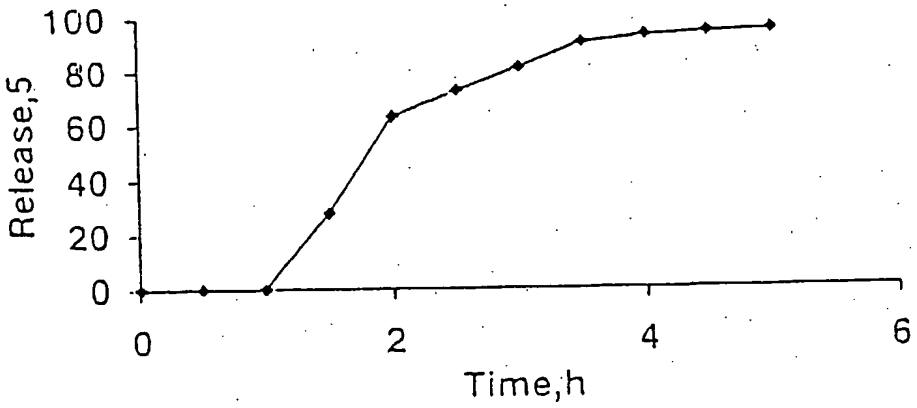


FIGURE 6

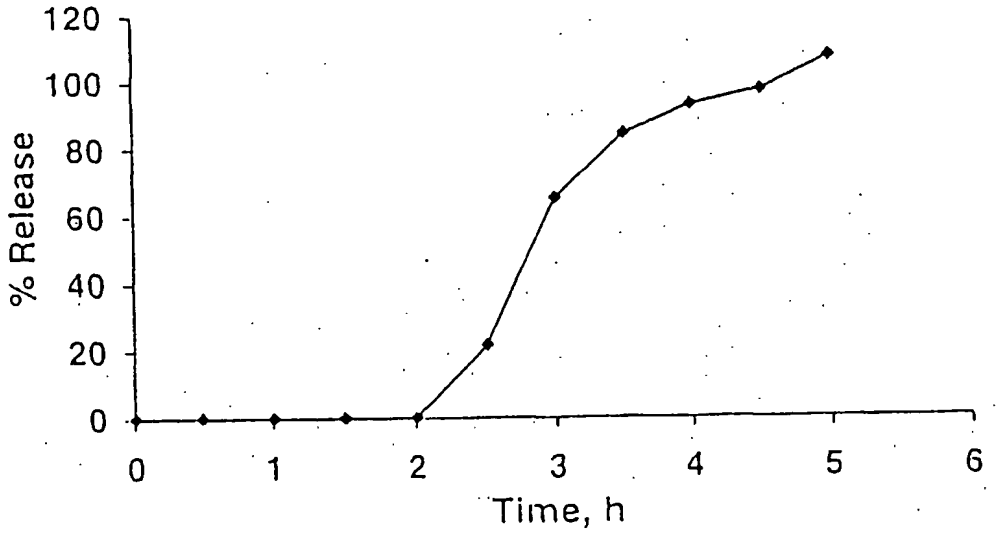


FIGURE 7

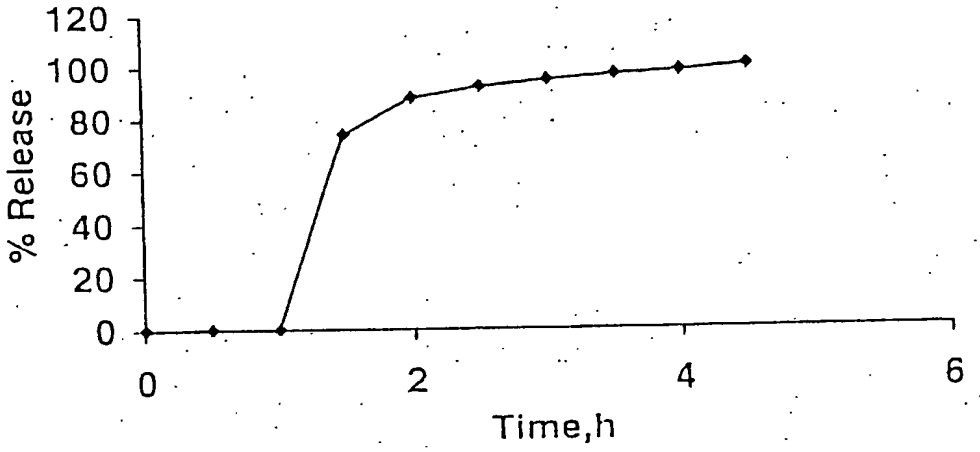


FIGURE 8

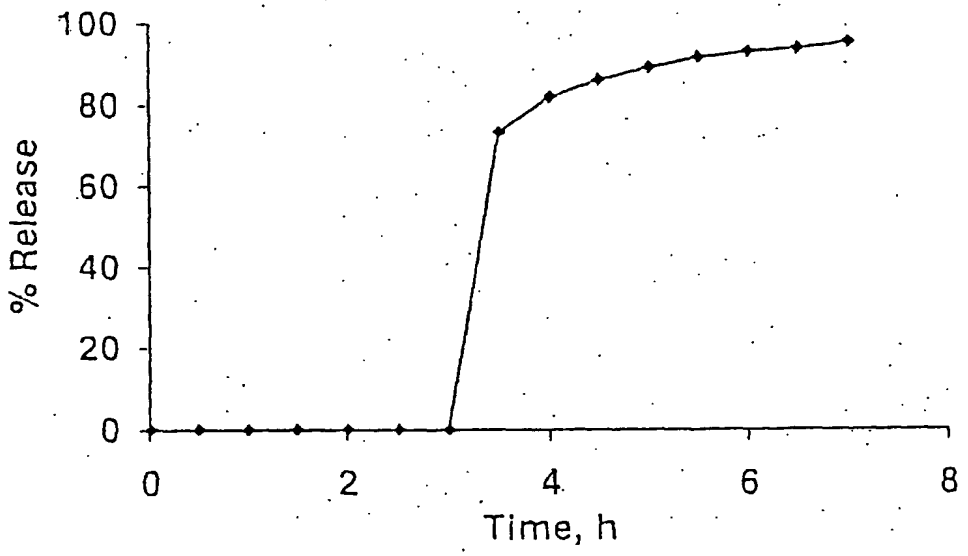


FIGURE 9

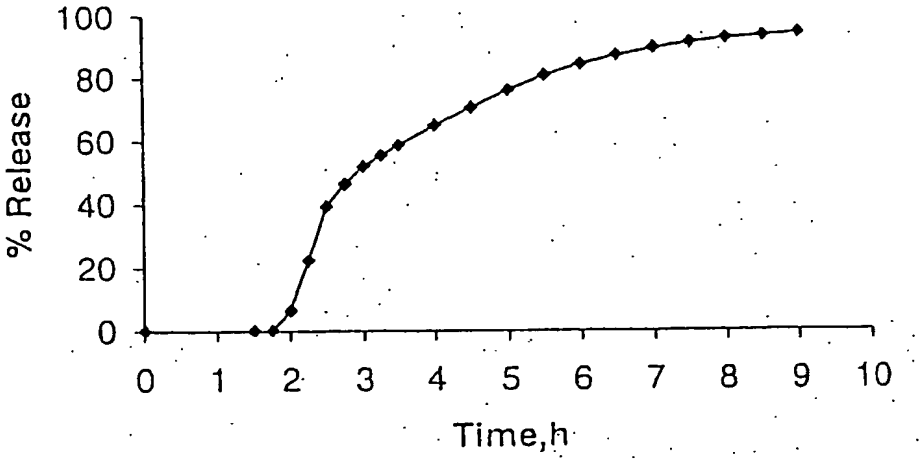


FIGURE 10

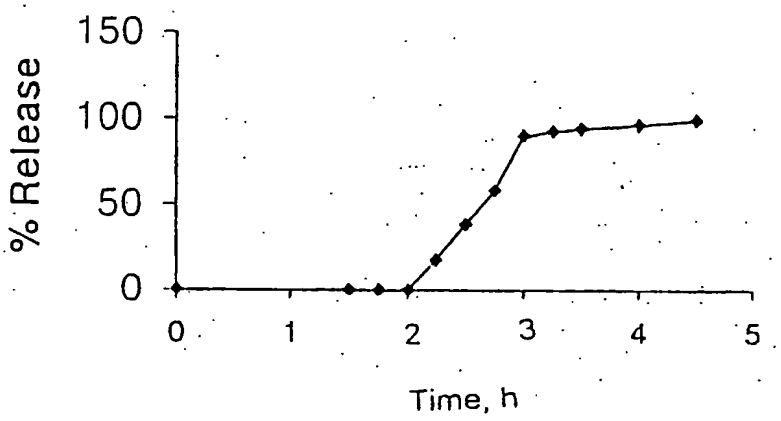


Fig. 11

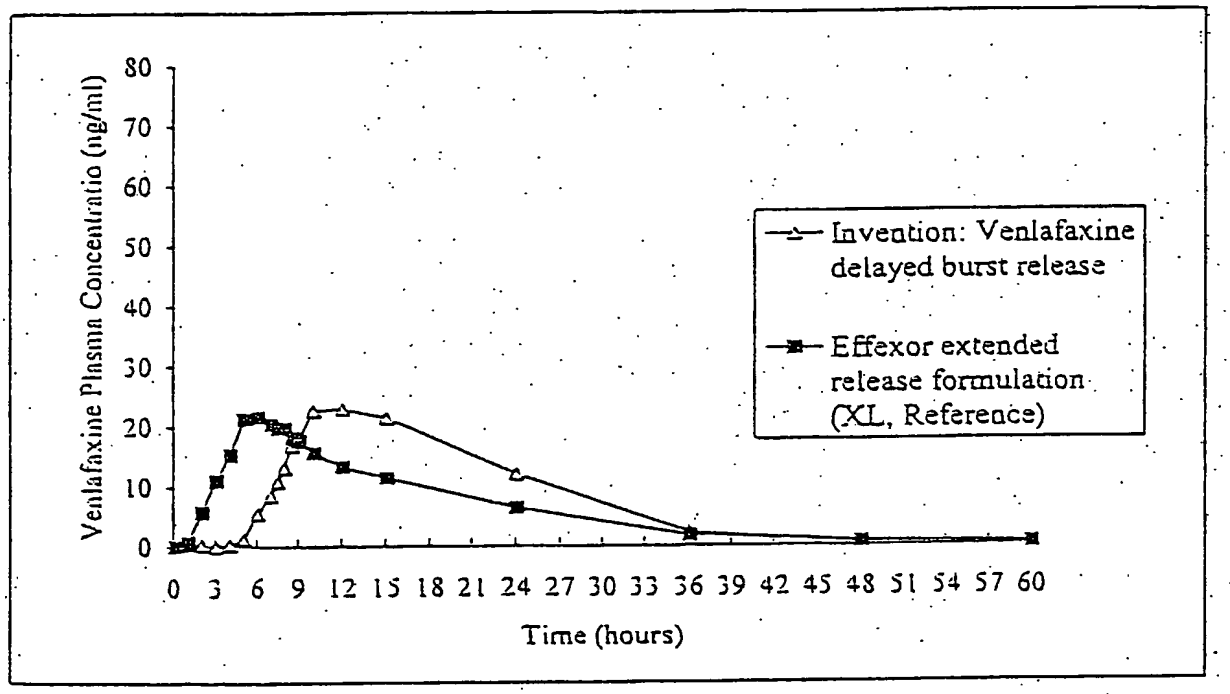

Venlafaxine Plasma Concentration (ng/ml)
80
70
60
50
40
30
20
10
0
0 3 6 9 12 15 18 21 24 27 30 33 36 39 42 45 48 51 54 57 60
Time (hours)
Invention: Venlafaxine delayed burst release
Effexor extended release formulation (XL, Reference)

FIG 12

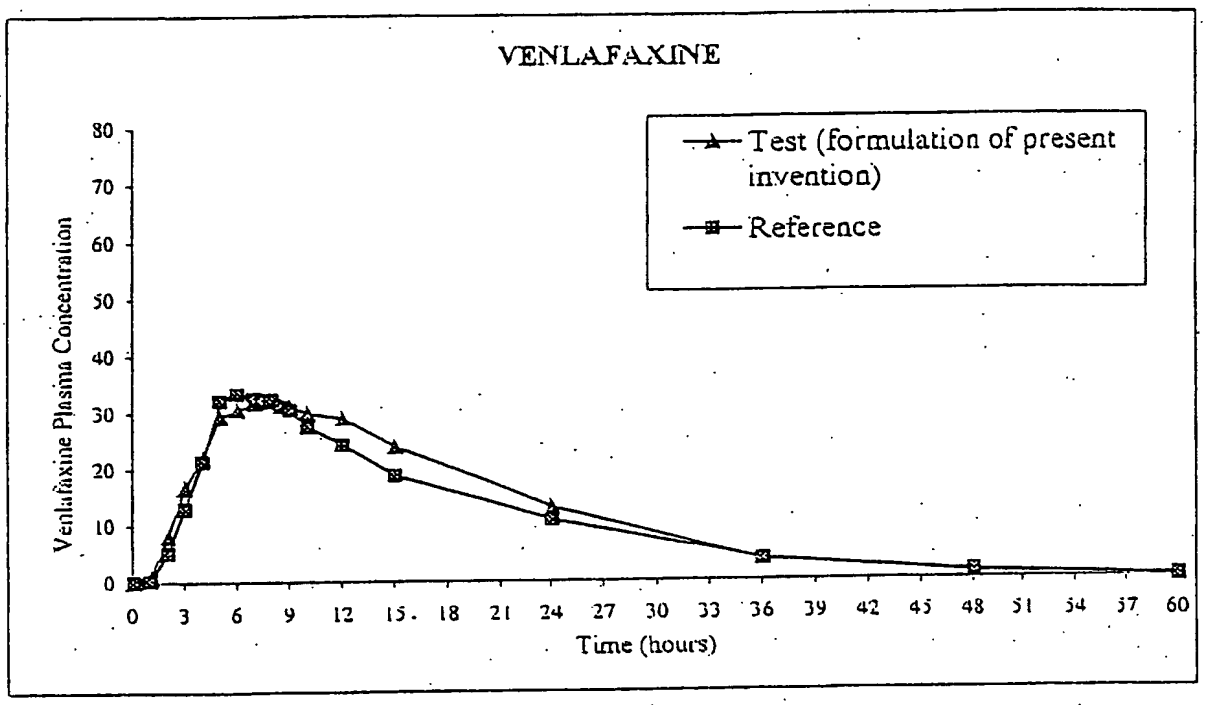

VENLAFAXINE
Test (formulation of present invention)
Reference
Venlafaxine Plasma Concentration
80
70
60
50
40
30
20
10
0
0 3 6 9 12 15 18 21 24 27 30 33 36 39 42 45 48 51 54 57 60
Time (hours)

FIG 13

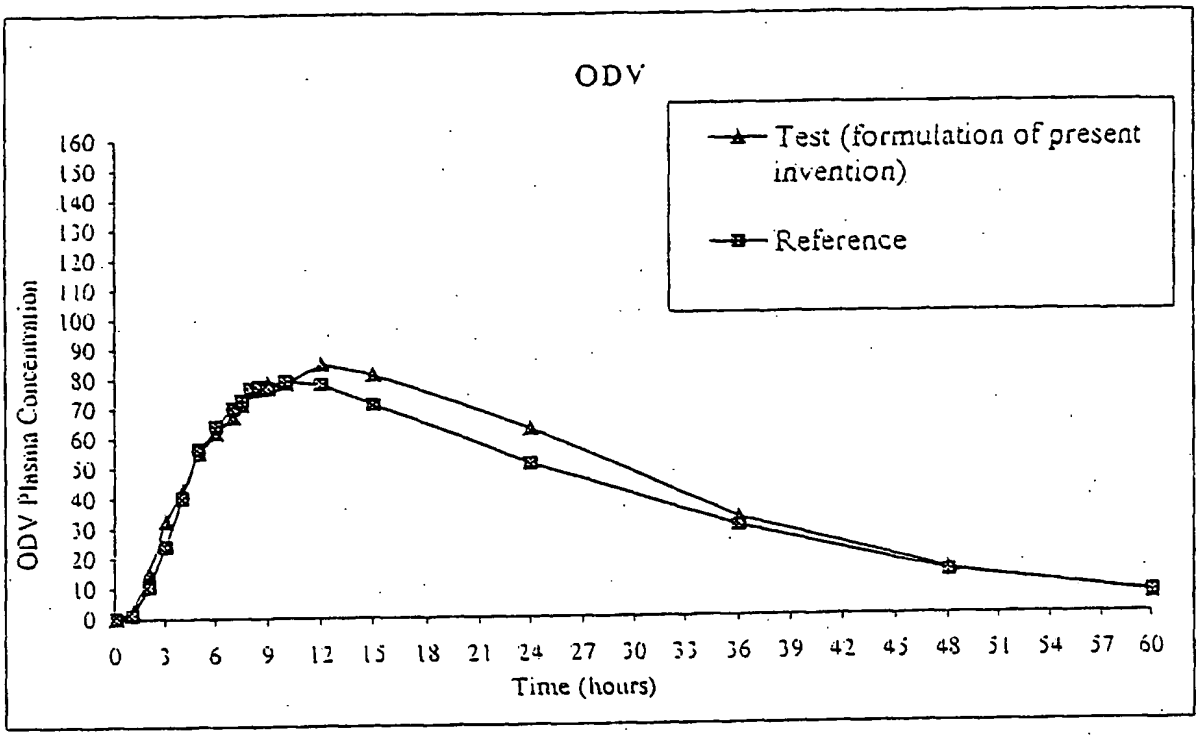

ODV
Test (formulation of present invention)
Reference
ODV Plasma Concentration
160
150
140
130
120
110
100
90
80
70
60
50
40
30
20
10
0
0 3 6 9 12 15 18 21 24 27 30 33 36 39 42 45 48 51 54 57 60
Time (hours)

FIG 14a

% Release

Time,h	#1	#2	#3	#4	#5	#6
0	0	0	0	0	0	0
1.25	0	0	0	0	0	0
1.5	0	0	0	0	0	0
1.75	0	0	0	0	0	0
2	0	0	0	0	0	0
2.25	71	70.9	68.1	47	82.3	57.4
2.5	75.6	99.4	74.4	65.9	87.3	68.2
2.75	78.6	105	78.5	69.9	89.7	73.7
3	81.3	106.9	81.6	73.2	91.5	77.8
3.5	85.5	107.3	86	78.2	93.8	85
4	89.2	107.5	89	82.5	95.5	90.8
4.5	92	107.5	91.2	85.8	96.4	95.3
5	94.4	107.7	93.1	88.6	97.1	98.6
5.5	96.5	107.7	94.7	90.8	97.8	101
6	98.2	107.8	95.9	92.7	98.2	103
7	100.3	107.9	97.6	95.7	98.8	105.6
8	101.7	108.3	98.5	97.7	99.3	107

FIG. 14b

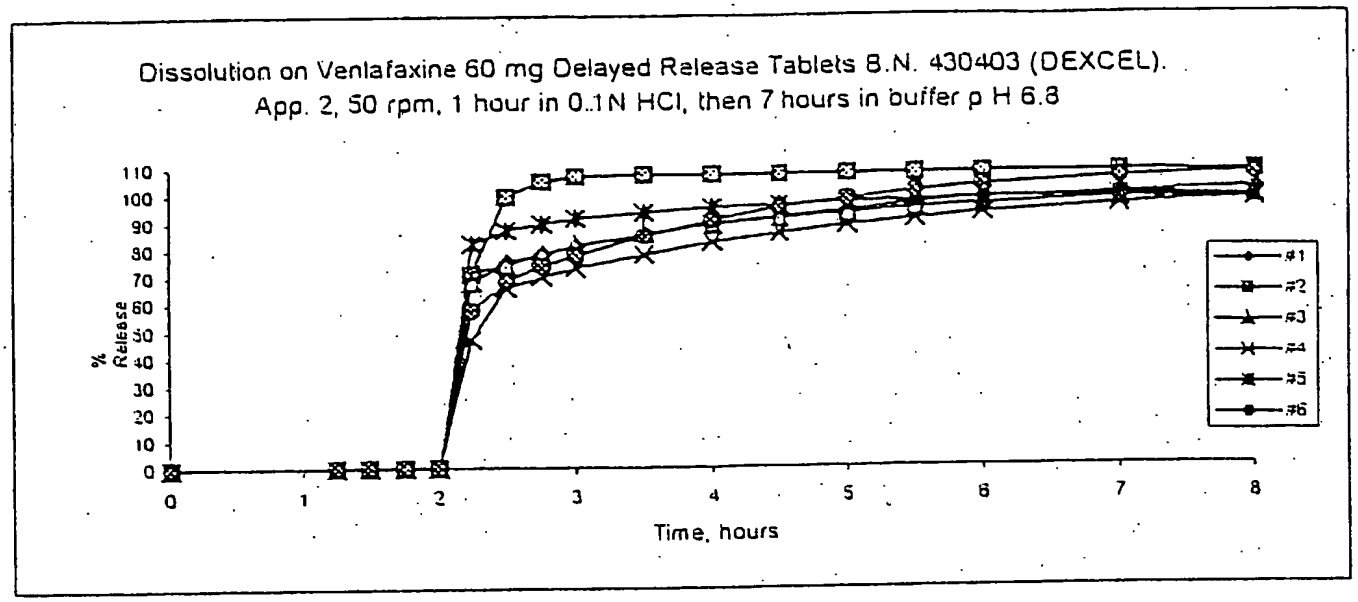

Dissolution on Venlafaxine 60 mg Delayed Release Tablets B.N. 430403 (DEXCEL).
App. 2, 50 rpm, 1 hour in 0.1N HCl, then 7 hours in buffer p H 6.8
% Release
110
100
90
80
70
60
50
40
30
20
10
0
0
1
2
3
4
5
6
7
8
Time, hours
#1
#2
#3
#4
#5
#6

FIG 15a

% Release

Time,h	#1	#2	#3	#4	#5	#6
0	0	0	0	0	0	0
1.25	0	0	0	0	0	0
1.5	0	0	0	0	0	0
1.75	0	0	0	0	0	0
2	0	0	0	0	0	0
2.25	0	0	10.1	0	0	0
2.5	29.8	81.9	81.2	56.2	76.8	64.3
2.75	85.8	87.2	86.1	72.9	82.3	73.9
3	91.2	97.2	88	80.5	86.4	77.8
3.5	94.7	101.0	91	88.9	91.5	82.8
4	96.3	101.8	93.7	93.6	94.6	87.2
4.5	97.6	103.4	95.6	96.6	96.4	90.8
5	98.8	104.2	97	98.4	97.7	93.7
5.5	99.3	104.6	98.2	99.8	98.2	95.6
6	100	105	99.1	100.6	98.5	96.8
7	100.6	105.9	100.1	102	98.9	98.5
8	101	106.2	101	102.6	99	100.4

FIG. 15b

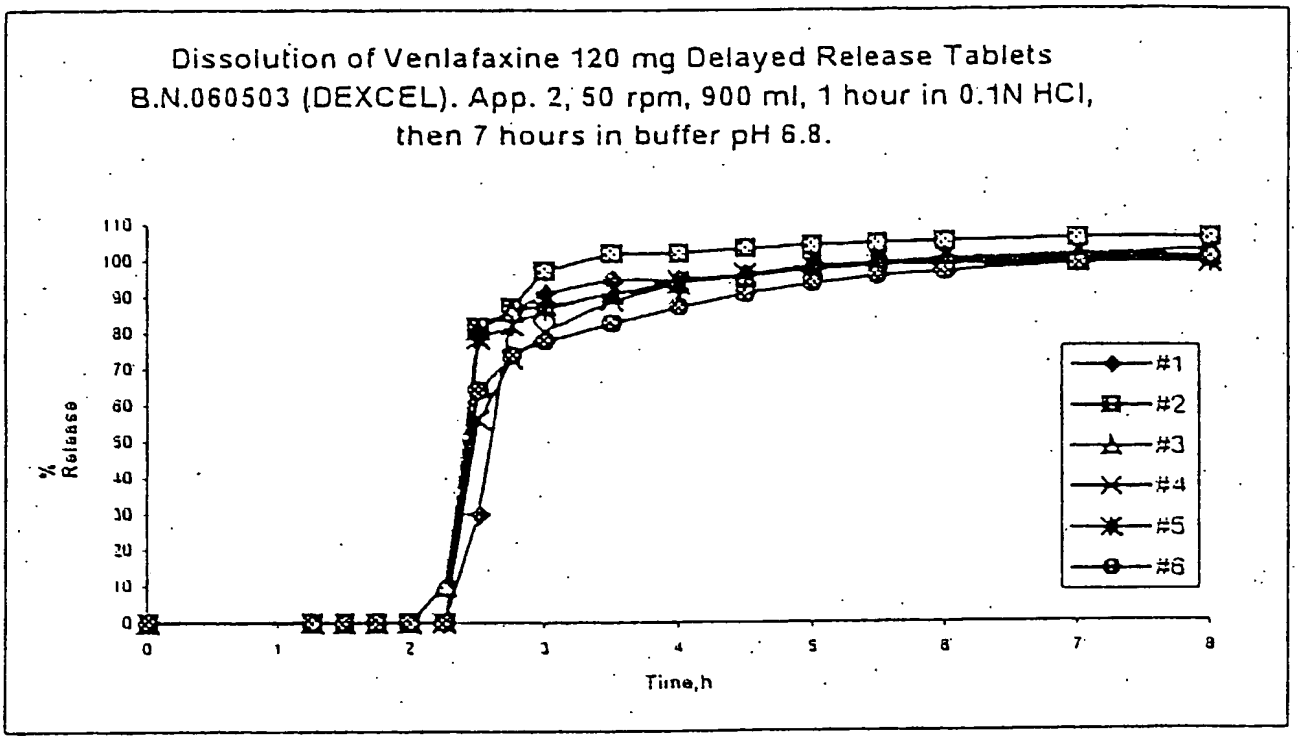
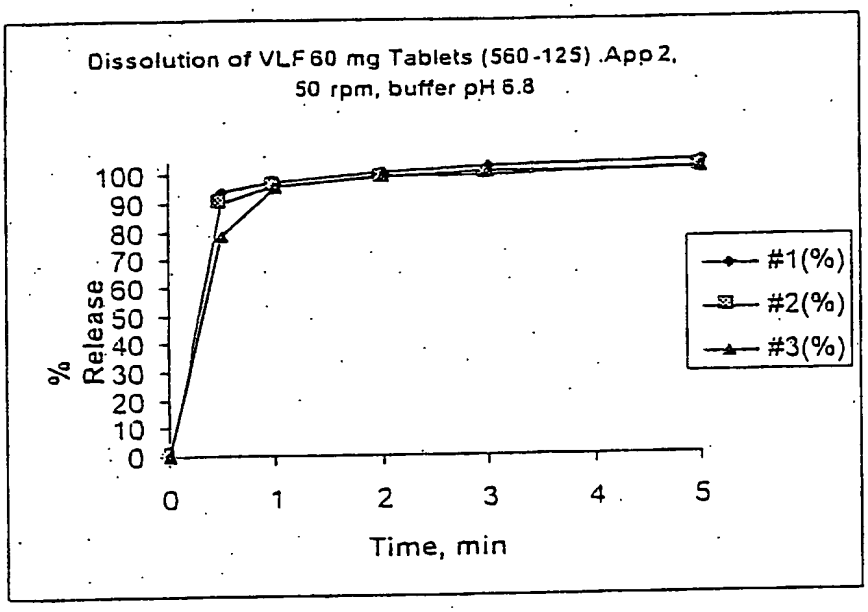

Dissolution of Venlafaxine 120 mg Delayed Release Tablets
B.N.060503 (DEXCEL). App. 2, 50 rpm, 900 ml, 1 hour in 0.1N HCl,
then 7 hours in buffer pH 6.8.
% Release
110
100
90
80
70
60
50
40
30
20
10
0
0
1
2
3
4
5
6
7
8
Time,h
#1
#2
#3
#4
#5
#6

FIG 16a

Time,min	#1(%)	#2(%)	#3(%)	Average(%)
0		0	0	0.0
0.5	94.2	90	78.6	87.6
1	97.4	96.1	95.5	96.3
2	101.2	98.7	99.5	99.8
3	102.7	99.5	101	101.1
5	104.1	101.3	101.4	102.3

FIG. 16b


Dissolution of VLF 60 mg Tablets (560-125) .App 2,
50 rpm, buffer pH 6.8
% Release
100
90
80
70
60
50
40
30
20
10
0
0
1
2
3
4
5
Time, min
#1(%)
#2(%)
#3(%)